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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,287	06/27/2001	Masahiro Kakehi	210098US0	1859

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/04/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/891,287

Applicant(s)

KAKEHI ET AL.

Examiner

Elizabeth Slobodyansky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4,5,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4 and 5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

The amendment filed January 8, 2003 (Paper No. 12) canceling claims 1-3 and 6-8, amending claims 4 and 5 and adding claims 9 and 10 has been entered.

Claims 4, 5, 9 and 10 are pending.

### ***Election/Restriction***

Newly submitted claims 9 and 10 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Inventions II and of claims 9 and 10 are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, genes that do not function normally are not necessarily disrupted. *Escherichia* cell can be used as a host cell for the recombinant production of various proteins. Furthermore, nucleoside 5'-phosphate ester can be produced by a different method such as chemical synthesis. This restriction is similar to the restriction between Group II and Group I in the Office action mailed July 9, 2002.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 9 and 10 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant's election of Group II, claims 4 and 5, in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Furthermore, the traverse is moot in view of the cancellation of claims 1-3 and 6-8.

### ***Claim Objections***

Claim 5 is objected to because of the following: Claim 5 recites "the nucleoside 5'-phosphate ester is selected from the group consisting of 5'-inosinic acid or 5'-guanylic acid" (emphasis added). "Acid" is not "ester". While the same compound maybe referred to, the use of one term would be consistent.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4, with dependent claim 5, recites "the genus *Escherichia*". The specification defines *E. coli ushA* gene as GenBank accession X03895 and *E. coli aphA* gene as GenBank accession X86971 (page 6, lines 18-20, and page 7, lines 16-22, respectively). The specification does not define sequences encompassed by the terms "*ushA* gene" or "*aphA* gene" of the genus *Escherichia* rendering the metes and bounds of the claim unascertainable.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Laird et al.

Laird et al. (form PTO-1449 filed March 5, 2002, reference AW) teach an *E. coli* mutant strain, 54G2, having non-functional *ushA* and *aphA* genes.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Thaller et al. alone or in view of Cowman et al.

Thaller et al. (form PTO-1449 filed September 26, 2001, reference AW) teach the sequence of the *aphA* gene (page 193, Figure 1). They further characterize 5'-nucleotidase activity of the *E. coli* AphA enzyme (page 195, Table 1). They teach that another 5'-nucleotidase in *E. coli* is UshA (page 197, 2nd column, last paragraph). They suggest producing strains carrying *aphA* mutations (page 198).

Cowman et al. (form PTO-1449 filed September 26, 2001, reference AV) teach the *ushA* gene from *E. coli* encoding a 5'-nucleotidase.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce *E. coli* mutants having non-functional, for example disrupted, *ushA* gene and *aphA* gene. The motivation to produce such mutants is provided by Thaller et al. who teach 5'-nucleotide dephosphorylating activity of *ushA* gene and *aphA* gene. Mutants with disrupted *ushA* gene and *aphA* gene would have a

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higher yield of 5'-nucleotides. One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success because the structures of both *ushA* gene and *aphA* gene were known at the time the invention was made and methods for disrupting known genes were widely used.

### ***Response to Arguments***

Applicant's arguments filed January 8, 2003 have been fully considered but they are not persuasive.

With regard to the 112, 2nd paragraph, Applicants argue that "the terms "ushA gene" and "aphA gene" have a well-defined and established meaning as evidenced by the description of those sequences in the prior art" (Remarks, page 2). The prior art references such as Thaller and Cowman define said genes, i.e. their sequences, in *E. coli*. However, it is not defined which sequences correspond to "ushA gene" and "aphA gene" in other species of the genus *Escherichia*. These sequences are not necessarily the same as the *E. coli* sequences. The relationship between "ushA gene" and "aphA gene" of the genus *Escherichia* and said genomic sequences in *E. coli* is not defined as well. Without knowing which sequences are encompassed by the claims, the metes and bounds of the claims are unascertainable.

With regard to 102(b) rejection, it is unclear from Applicants' Remarks on page 3 why *E. coli* strain 54G2 described by Laird et al. that has non-functional *ushA* and *aphA*

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genes does not anticipate claims 4 and 5. In other words, it is unclear what renders *E. coli* strain 54G2 different from the claimed bacterium because it has both *ushA* gene and *aphA* gene disrupted.

With regard to 103(a) rejection, Applicants argue while discussing the Thaller et al. and Cowman et al. references that “therefore, even if one assumes that it would have been obvious to disrupt both genes, there would not have been an expectation that disrupting both genes rather than each individually would facilitate the production of nucleoside 5'-phosphate esters. This is particularly so in light Thaller et al who describes the *aphA* gene is a physiological equivalent of *ushA* gene” (page 5). This is not agreed with because it appears that “particularly so in light Thaller et al who describes the *aphA* gene is a physiological equivalent of *ushA* gene”, there would have been an expectation that disrupting all genes known to encode the same activity would result in eliminating of said activity. The disruption of only some genes would leave others producing the activity.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within



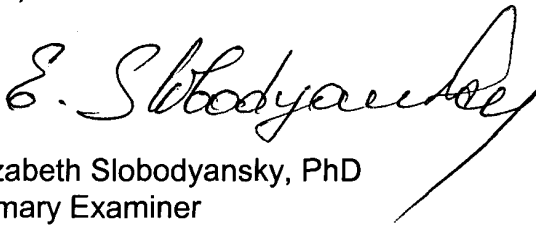
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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.



Elizabeth Slobodyansky, PhD  
Primary Examiner

April 3, 2003